

Attorney Docket No.: PENN-0754  
Inventors: Scott L. Diamond  
Serial No.: 09/763,982  
Filing Date: April 25, 2001  
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**REMARKS**

Claims 1-13 are pending in this application. Claim 8 has been acknowledged to be allowable. Claims 1-7 and 9-13 have been rejected. Claims 4 and 11 have been amended. Claim 13 has been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Acknowledgment of Previous Response to Arguments**

The Examiner has acknowledged that the previous amendment, submitted on January 31, 2003, successfully overcame the rejections under 35 U.S.C. § 102.

**II. Rejection of Claims under 35 U.S.C. § 112**

The Examiner has rejected claims 1, 2, 4, 5, 7 and 9-13 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. The Examiner suggests that claims 1, 2, 4, 5, 7 and 9-13 are drawn to the genus of non-classical nuclear

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localization signals (NLSs) that do not interact with importin alpha or importin beta. The claims are suggested to recite no structural limitations and the genus is suggested to be defined on the basis of functional characteristics. The Examiner suggests that the specification discloses three non-classical NLSs by name, M9, KNS and HNS. The Examiner suggests that the sequences of allelic homologous or orthologous NLS would be impossible to predict. As such, the Examiner suggests that one of skill could not conclude that Applicant was in possession of the claimed genus at the time of the invention. Applicant respectfully disagrees.

Applicant respectfully submits that in view of the Examiner's previous comments, and as fully supported and clearly defined in the specification at pages 8, line 6 through page 9, line 25, the nuclear targeting peptide of the instant invention is one which does not contain a classical nuclear localization signal, and hence is nonclassical.

MPEP §2163 states that for some biomolecules, examples of identifying characteristics include a sequence structure, binding affinity, binding specificity molecular weight, and length. The MPEP further recites that although structural formulas provide a convenient method of demonstrating possession of specific

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molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession.

Applicant respectfully submits that in view of the Examiner's previous comments, and as fully supported in the specification at page 8, line 6 through page 9, line 25, the structure of the nuclear targeting peptide is one which does not contain the classical nuclear localization signal, and hence is nonclassical. Applicant further submits that the criteria required by MPEP §2163 is fully met by the written description provided in the specification, because at the time of filing one of skill in the art would understand the terminology nonclassical nuclear localization signal as defined in the specification.

Further, Applicant has provided multiple examples of typical nonclassical nuclear localization signals, see page 8, lines 9-11. Under MPEP 2163, what constitutes a representative number is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Applicant respectfully submits that as disclosed

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by the specification at page 8, lines 6-14, and by the multiple examples of nonclassical nuclear localization signals, the nonclassical NLSS of the present invention demonstrate the common attribute of non-interaction with importin- $\alpha$  and importin- $\beta$ .

Reconsideration and withdrawal of these rejections under 35 U.S.C. §102 (b) is therefore respectfully requested.

### **III. Enablement**

Claims 1, 2, 4, 5, 7, and 9-13 are rejected under 35 U.S.C. 112, first paragraph because it is suggested that the specification while acknowledged as enabling for compositions comprising nuclear localization peptides comprising SEQ ID NOS: 3 or 4 wherein the peptides do not interact with importin alpha or importin beta, does not reasonably provide enablement for the broader genus of all nuclear localization peptides that do not interact with importin alpha or importin beta. The Examiner suggests that the specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected to make or use the invention commensurate in scope with these claims. The Examiner suggests that one of skill in the art would have to perform empirical experimentation in order to make non-classical

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NLSs other than SEQ ID Nos 3 and 4. The Examiner suggests that the specification adequately enables only those compositions and methods that require the use of NLSs comprising SEQ ID NOS: 3 and 4. Applicant respectfully disagrees.

MPEP §2146.08 recites that "not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003)

The Examiner further suggests that the specification fails to enable the full scope of claims 4-6, and 11 as these claims are

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drawn to methods of delivering a selected molecule to the nucleus of a eukaryotic cell wherein the method requires contacting cells with the molecule and with a nuclear targeting peptide containing a non-classical nuclear localization signal. The claims are suggested to require no physical linkage between the molecule and the targeting peptide. The specification is acknowledged to teach means for associating molecules with targeting peptides and methods of using the resulting complexes to deliver the associated molecules to cell nuclei. It is suggested that the specification fails to teach how to deliver molecules to the nucleus of cells that have been, or will be contacted with a nuclear targeting peptide that is not in some direct or indirect fashion attached to the molecule. The Examiner suggests that the claims are enabled only for the scope of the invention in which the targeting peptide is in some way attached to the selected molecule. Applicant respectfully disagrees.

However, in an earnest attempt to facilitate prosecution, claims 4 and 11 have been amended in accordance with the Examiner's suggestion to clarify that the cells are contacted with a composition comprising the selected molecules contacted with a nuclear targeting peptide. Support for this amendment is found

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throughout the specification and at page 11, line 11 through page 12, line 2, and at page 13, lines 30-31.

Claim 13 is rejected under 35 USC 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, as the metes and bounds are unclear. Applicant respectfully disagrees. However, in an earnest attempt to further facilitate prosecution of this application, claim 13 has been canceled.

#### **IV. Claim rejections under 35 USC 102**

Claim 13 is rejected under 35 USC 102(b) as being anticipated by Jost et al. (Nucl. Acids Res. (1997) 25(15):3131-3134).

Jost is suggested to teach cells stably transfected with a plasmid. Jost is considered to anticipate the claims because the claim does not require the presence in the cell of a complex comprising a scaffold-nuclear targeting peptide conjugate. Rather the claim is a product-by-process claim that is anticipated by any stably transfected cell comprising a plasmid. This is because the recited scaffold-nuclear targeting peptide conjugate is composed of biodegradable materials that would not be expected to persist in a

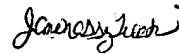
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cell line that is maintained in continuous culture. Applicant respectfully disagrees with this rejection. However, Applicant's cancellation of claim 13 has hereby rendered this rejection moot. Applicant respectfully requests withdrawal of this rejection.

**V. Conclusion**

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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